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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097348,469	07/07/99	SMITH	04999-0001-1

HM12/0313
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ZARA, J	EXAMINER
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ART UNIT 1635	PAPER NUMBER
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DATE MAILED: 03/13/01 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/348,469

Applicant(s)

SMITH ET AL.

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-29, 32-34, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-29, 32-34, 41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

This Office action is in response to the communication filed September 29, 2000, Paper No. 7.

The Notice of Non-Response mailed December 18, 2000, Paper No. 8, is hereby vacated and a new Office action clarifying the previously recited scope of enablement rejection of Paper No. 5, mailed March 30, 2000, is set forth below.

Claims 22-29, 32-34, 41 and 42 are pending in the instant application.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

Amended claim 34 is objected to because of the following informalities: It appears that the word --that-- should be inserted before "has" in line 3. Appropriate correction is required.

Response to Arguments and Amendments

Retained Rejections

Claims 22-29, 32-34 and new claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement over the scope claimed, for the same reasons of record as set forth in the Office action mailed March 30, 2000, Paper No. 5.

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Support has been provided in the instant specification for a method of inserting a heterologous gene coding sequence into an endogenous gene in a mouse embryonic stem cell and subsequently expressing the heterologous gene comprising transforming the host mouse stem cell with a random gene trap vector comprising the sequence 5'-X-A-P-B-Q-C-Y-3', where X comprises a splice acceptor sequence, Y comprises a polyadenylation signal, P comprises the encephalomyocarditis virus internal ribosome entry site (IRES), and Q comprises the heterologous gene sequence which includes a translation start codon, and A, B and C comprise optional linker sequences, and further whereby the gene which is targeted in the mouse embryonic stem cell is normal Differentiation Inhibiting Activity/Leukaemia Inhibitory Activity gene. Such experimental support provided in the instant specification is not representative of the scope of the claimed invention, and is not correlative or representative of a method of inserting a heterologous gene coding sequence into any endogenous gene in any eukaryotic host cell genome, whereby the method comprises transforming any host cell with a random gene trap vector comprising a splice acceptor sequence, a polyadenylation signal, any internal ribosome entry site, a heterologous gene sequence, and optional linker sequences, whereby any endogenous gene is successfully targeted in any host cellular genome, and further whereby successful heterologous gene translation is obtained in any host cell comprising transformation with a gene trap vector comprising any internal ribosome entry site. One skilled in the art would not accept on its face the examples given of the ability to target the normal Differentiation Inhibiting Activity/Leukaemia Inhibitory Activity gene in the mouse genome in mouse embryonic stem

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cells using the gene trap vector of the instant invention comprising the encephalomyocarditis virus internal ribosome entry site as being correlative or representative of the ability to insert and express a heterologous gene in any host organism's genome using a gene trap vector comprising any internal ribosome entry site and further targeting any endogenous gene in any host's genome. In order to practice the invention over the scope claimed, the de novo determination must be made concerning the compatibility of gene trap vectors comprising different internal ribosome entry sites with different target cell types whereby heterologous gene expression is obtained. Furthermore, the de novo determination of the ability to target different endogenous gene targets must be made using such gene trap vectors whereby heterologous gene expression is obtained upon insertion of the gene trap vector into various endogenous gene targets in the genomes of various hosts.

Any rejection not repeated herein is hereby withdrawn.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be

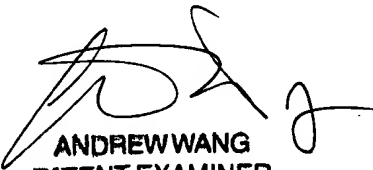
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retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

March 7, 2001


ANDREW WANG
PATENT EXAMINER
TC1600